

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

)	MDL No. 1456
IN RE PHARMACEUTICAL INDUSTRY)	Master File No. 01-12257-PBS
AVERAGE WHOLESALE PRICE LITIGATION)	
<hr/>)	Judge Patti B. Saris
)	
THIS DOCUMENT RELATES TO:)	
State of California, <i>ex rel.</i> Ven-A-Care v.)	
Abbott Laboratories, <i>et al.</i>)	
03-CV-11226-PBS)	
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PLAINTIFFS' OBJECTIONS TO DEFENDANTS' SUPPLEMENTAL BRIEF

Plaintiffs object to Defendants’ Supplemental Brief (SB) filed June 12, 2006. A hearing on Defendants’ Motion to Dismiss (MTD) was completed on May 22, 2006. There is nothing “supplemental” in Defendants’ brief, which transparently and improperly lobbies for a purported “meaning” from three selectively culled documents improperly attached to their MTD under the guise of a procedurally and legally defective request for judicial notice. Defendants engineer a pretext for more argument under the opaque premise that based on “comments at the [May 22, 2006] hearing . . . the Court may be under the mistaken impression that AWP and DP were always defined by the California legislature.” SB at 1. They proceed under the unremarkable observation that “Average Wholesale Price” (“AWP”) and “Direct Price” (“DP”) were not statutorily defined until 2002. *See* CAL. WELF. & INST. CODE § 14105.46 (repealed August 16, 2004, with AWP and DP definitions incorporated into amended CAL. WELF. & INST. CODE § 14105.45.) AWP and DP appear in Title 22 of the California Code of Regulations, section 51513. Plaintiffs have comprehensively explained the Title 22 regulatory framework regarding the

utilization of the terms AWP and DP. *See* FAC ¶¶ 27, 28, 32 (explaining reimbursement under section 51513); and Plaintiffs' Opposition to MTD, pp. 16-17. Plaintiffs noted the 2002 and 2004 amendments to CAL. WELF. & INST. CODE §§ 14105.46 and 14105.45. (Opp. at 16, n.10) There is no "mistaken impression" left before the Court.

In their SB, Defendants again argue that two 1987 price lists in exhibit E show California's supposed acceptance of their bloated AWP's. Even if this Court decides it should go beyond the First Amended Complaint in considering extrinsic materials in interpreting the California statutory and regulatory framework, none of the exhibits assist in that objective. They do not provide the Court with a remotely comprehensive regulatory or legislative record. Exhibit E consists of a small fraction of all the price lists considered by DHS in 1987 (*see* Ex. F, pp. 2-3); Defendants chose not to attach the other lists. The extract at exhibit E compares AWP's to selected market prices, and exhibit F simply explains how DHS intended to implement the (then-newly announced) federal FUL requirement, in particular by applying the FUL limit to drug products which were available to providers from a wholesaler at an AWP *which was at or below the FAC* [i.e. FUL] price. *Id.* at 1-2. DHS self-evidently construed AWP as tethered to "real" market prices, since it looked to ensure that pharmacists could *obtain* drugs at a particular AWP:

" . . . that California pharmacists can actually obtain such drug products at an AWP which is at or below the [FUL] price . . . the important consideration is whether the drug product is available at or below the [FUL] price . . . [even if] obtaining the drug product at such price may sometimes require pharmacy providers to utilize a different wholesaler than the provider usually buys from."

Ex. F at 2. The long-standing regulation mirrors the more recent statute: "EAC for a drug product means the Department's best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard

package. The EAC for a drug product shall be [DP or AWP minus percentage]." Cal. Code Regs. tit. 22, § 51513. Finally, nothing in exhibit A is indicative of regulatory intent regarding DHS's employment of the terms "AWP" and "DP" as reimbursement criteria.

Respectfully submitted,

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Dated: June 20, 2006

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CERTIFICATE OF SERVICE

I, Nicholas N. Paul, hereby certify that on June 20, 2006, I caused a true and correct copy of the foregoing, **PLAINTIFFS' OBJECTIONS TO DEFENDANTS' SUPPLEMENTAL BRIEF** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: June 20, 2006

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